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09/424,951	01/20/2000	THYAGARAJAN SRIKANTHA	087714-0113	8877

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EXAMINER

LAMBERTSON, DAVID A

ART UNIT PAPER NUMBER

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28

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/424,951

Applicant(s)

SRIKANTHA ET AL.

Examiner

David A. Lambertson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 19 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 16 and 20 is/are allowed.
- 6) ☐ Claim(s) 1-15 and 17-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 20 January 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application)  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449; Paper No(s) \_\_\_\_\_)
- 4) ☐ Interview Summary (PTO-413; Paper No(s) \_\_\_\_\_)
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other

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### **DETAILED ACTION**

Receipt is acknowledged of a reply, filed February 19, 2002 as Paper No. 27, to the previous Office Action. Amendments were not made to the claims.

Claims 1-20 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, Paper No. 16, mailed April 23, 2002, that is not addressed in this action has been withdrawn.

Applicant's declaration concerning the deposit of biological material has been considered and is found to satisfy the deposit requirements made under the Budapest Treaty.

The Finality of the previous Office Action, mailed April 23, 2002 as Paper No. 16, is withdrawn and prosecution is re-opened for the instant application. The instant claims contain outstanding rejections that were not made in the previous Office Action, and must be addressed prior to allowance.

### ***Drawings***

New corrected drawings are required in this application because of the reasons set forth in the Draftsperson's review, form PTO-948 mailed April 24, 2001 with Paper No. 10. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

It is noted that this paragraph was not included along with the Office Action accompanying the previous PTO-948. However, in order for a response to be considered

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complete in response to this Office Action, the response must include corrected drawings as set forth in the previous PTO-948.

### ***Claim Objections***

Claims 17 and 18 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 17 and 18 recite the limitation of low and moderate stringency conditions as it relates to polynucleotides hybridizing under stringent conditions. Both of these limitations appear to broaden the scope of polynucleotides that are claimed, therefore the claims do not further limit the parent claim.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-15, 17 and 18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims an isolated polynucleotide, encoding a protein with a function in phenotypic switching, wherein the nucleotide exhibits 70% , 80% or 90% or greater identity to

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the isolated polynucleotide of SEQ ID NO: 3, or where the polynucleotide hybridizes under low or moderately stringent conditions. The claims read on a broad genus of polynucleotides encoding a protein having a function of phenotypic switching, without disclosing the relevant features of the polynucleotide encoding the protein that entail this function.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics sufficient to show applicants were in possession of the claimed genus. In the instant case, the specification does not disclose the relevant identifying characteristics of the sequence that relates to the claimed function.

Applicant claims polynucleotide sequences having greater than 70-90% identity to SEQ ID NO: 3 or that hybridize under low or moderate stringent conditions by function only, without any disclosed or known correlation between the sequences and their function. The specification only provides teachings regarding the full-length sequence and its role during phenotypic switching by virtue of deleting the entire sequence. The specification does not teach what specific domains of SEQ ID NO: 3 are required for the function of phenotypic switching by demonstrating what particular regions domains or nucleotides amino acids can be mutated while maintaining the function. In essence, the specification does not teach what regions must maintain the at least 70%, 80% or 90% identity with SEQ ID NO: 3 in order to function during phenotypic switching. This also relates to the claims as they regard hybridizing under low or moderately

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stringent conditions. Since low to moderate stringency conditions relate to a large number of differences in sequences, it is likely that loss of function of the protein can occur with a number of polynucleotides that hybridize under low and moderate stringent conditions. In the absence of knowing what domains are required for this function, it is impossible for the ordinary skilled artisan to envision sequences that hybridize under low and moderate stringency conditions and still retain the function of "phenotypic switching." As a result, the skilled artisan cannot envision a sufficient number of embodiments of the instant invention from the instant specification, and therefore cannot determine if they have either infringed upon the instant invention or made an improvement.

The prior art does not provide sufficient information on the subject to overcome the deficiencies of the instant specification. There is no description in the prior art that allows one to envision a representative number of polynucleotides having at least 70%, 80% or 90% identity with SEQ ID NO: 3 of the instant invention by disclosing structural or functional features of this polynucleotide so that one of skill in the art could identify said sequences as claimed. It is unclear from the prior art what sequences must maintain the at least 70%, 80% or 90% identity with SEQ ID NO: 3 in order to maintain a phenotype switching function. Similarly, it is impossible to envision from the prior art which sequences that hybridize under low and moderately stringent conditions would also retain this function. Thus the skilled artisan cannot rely on the prior art to envision a sufficient number of embodiments of the instant invention to see that the applicant was in possession of the claimed genus.

Neither the specification of the instant application or the prior art teaches a structure-function relationship for a polynucleotide having at least 70%, 80% or 90% identity with SEQ ID

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NO: 3. As a result, the skilled artisan would not be able to envision the claimed invention by relying on the teachings of the prior art or the instant specification. Therefore the specification does not satisfy the written description requirement to show the skilled artisan that they were in possession of the claimed genus.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 and 17-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite the limitation that a polynucleotide hybridizes under stringent conditions. Applicant provides a definition that *generally* applies concerning "stringent conditions" on pages 6-8 of the instant specification. However, the definition does not clearly set forth the metes and bounds of the sequences that are encompassed by the claims. This is because the definition only recites information about determining hybridization conditions in general, and the language does not clearly indicate that these specific conditions apply to the instant invention. Furthermore, it is unclear if the term "stringent hybridization" encompasses those sequences that would hybridize under low and moderately stringent conditions, especially in light of the dependent claims 17 and 18 (see below).

Claims 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 17 and 18 recite the limitation of low and moderate stringency conditions as it relates to polynucleotides hybridizing under stringent conditions. Both of these

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limitations appear to broaden the scope of polynucleotides that are claimed, therefore the metes and bounds of the claim are not defined.

*Allowable Subject Matter*

Claims 13-15 stand rejected. Claims 16 and 20 are allowable over the prior art and in consideration of applicant's declaration under 37 CFR 1.131, filed July 24, 2001 as Paper No. 11.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson  
March 18, 2003

  
DAVID A. LAMBERTSON  
PRIMARY EXAMINER